AMENDMENTS TO THE SPECIFICATION

Replace the "BRIEF DESCRIPTION OF THE FIGURES" section (paragraphs [0012]-[0026] of the published application) with the following:

BRIEF DESCRIPTION OF THE FIGURES

FIG. 1 ~~is a series of figures relating to a preferred device and method of the present invention using a model skull. Although the expansion means is depicted as metal, the expansion device can be made in whole or in part of a biodegradable, bioerodible or bioresorbable material. Such expansion means can be made by tooling or molding such biodegradable, bioerodible or bioresorbable materials, as was used to make the screws depicted in this series of figures. Such methods of making can be selected based on the characteristics of the material and the forces under which the device is placed during operation. The expansion means can also take for form of a screw, a worm gear, a rack and pinion or a ratchet.~~

~~**FIG. 1A** depicts a region of a skull that has undergone an osteotomy to fully free a portion of the "cheek bone."~~

~~**FIG. 1B** depicts two portions of a transmitting means that includes a macroporous sheet of PLA/PGA and a flange-engaging structure suitable for engaging a flange of an expansion means.~~

~~**FIG. 1C**~~ is a perspective view depicting ~~depicts~~ the two portions of a transmitting means being engaged using PLA/PGA screws.

FIG. [[1D]] 2 is a plan view depicting ~~depicts~~ two transmitting means of **FIG. 1[[C]]** engaged with an expansion means ~~made of metal~~.

FIG. ~~1E and FIG. 1F~~ depicts 3 is a perspective view depicting the nature of the engagement of the transmitting means and the expansion means as reversible.

~~**FIG. 1G** depicts the proximal transmitting means : expansion means : distal transmitting means that has been trimmed and configured for use on the osteotomy depicted in **FIG. 1A**. Note that the proximal transmitting means has been altered from its planar configuration.~~

~~**FIG. 1H** depicts the heat malleable nature of a transmitting means. The proximal transmitting means is contacted with water hot enough to induce malleability of the material and the shape of the material is changed to conform to the shape of the region to which it will be attached.~~

FIG. ~~1H and FIG. 1J~~ 4 is a perspective view depicting ~~depict~~ the distraction device in place at the site of osteotomy. The transmitting means are secured to the skull using PLA/PGA screws in holes drilled into the bone. During a distraction procedure, the implementation of the distraction device would be complete. Distraction would be accomplished by engaging the expansion means with an activation means to gradually increase the distraction distance.

FIG. [[1K]] 5 is a perspective view depicting ~~depicts~~ the distraction device after distraction has taken place. This figure depicts a mock-up skull, thus the distraction space has not been filled with distraction tissue. At the point in the procedure, the expansion means would be removed by disengaging the expansion means from the transmitting means, such as by engaging the activation means to decrease the length of the expansion device. The expansion means can be removed using surgical procedures, preferably endoscopic procedures. If the expansion means is made in whole or in part of biodegradable, bioerodible or bioresorbable materials, then the expansion means can optionally be removed. Optionally, at least one stabilizer can be inserted into, over or around the expansion space and appropriately secured such that the distracted tissue is mechanically stabilized. Such stabilizer(s) are preferably made at least in part of biodegradable, bioerodible or bieresorbable material, such as PLA/PGA, preferably macroporous PLA/PGA.

FIGS. [[1L]] 6A, 6B and **6C** are top, bottom and side views depicting a flange-engaging structure of ~~depicts~~ a transmitting means of one aspect of the present invention that includes structures to engage an expansion means.

FIG. [[2]] 7 is a conceptual diagram depicting the use of stabilizing means in a distraction procedure ~~depicts a unidirectional distraction device that includes "shark's tooth" and indentations to allow unidirectional sliding of the transmitting means~~.

FIG. [[3]] 8 is a conceptual diagram depicting ~~depicts~~ the use of guiding means to direct the vector of distraction.

FIG. [[4]] 9 is a conceptual diagram depicting ~~depicts~~ the use of stabilizing means in a distraction procedure.

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FIG. [[5]] 10 is a conceptual diagram depicting ~~depicts~~ the use of engaging structures, such as in a "shark's tooth" configuration, that allows members of the distraction device to slide against each other in a unidirectional manner, which can also serve to stabilize the distraction device itself.

Amend the paragraph beginning on page 10, line 10 section (paragraph [0040] of the published application), to read as follows:

A transmitting means 10A, 10B (collectively 10) can be made of one or more components that can be engaged to form a transmitting means, such as set forth in ~~FIG. 1~~**FIGS. 1 and 2.** The transmitting means preferably engages an expansion means 12 such that distraction is enabled by separating a first transmitting means 10A from a second transmitting means 10B by an expansion means 12 such as set forth in **FIG. [[1]] 2**.

Amend the paragraph beginning on page 17, line 12 (paragraph [0063] of the published application), to read as follows:

In one aspect of the present invention, the first transmitting means 10A and the second transmitting means 10B comprise structures that allow the transmitting means 10 to slide unidirectional across each other. The two transmitting means 10 can slide along a single vector 14 or multiple vectors based on the particular structures used. For example, the first transmitting means 10A can comprise engaging structures designed to engage mating structures on the second transmitting means 10B. For example, the first transmitting means 10A can comprise a plurality of indentations, hole, protrusions, "shark's teeth" or other structures that can engage mating structures on the second transmitting means 10B such as indentations, holes, protrusions or other structures. Preferably, the engaging structures are indentations or holes 16 and the mating structures are protrusions such as pins or shark's teeth structures 18. Alternatively, the engaging structure and the mating structure are shark's teeth structures. As the two transmitting means slide across each other in one direction 14, they engage such that they preferentially do not slide in a different direction. One preferred example of the aspect of the invention is depicted in **FIG. [[2]] 10**.

Amend the paragraph beginning on page 17, line 25 (paragraph [0064] of the published application), to read as follows:

In another aspect of the present invention, the connective tissue distraction device includes guiding means 20 to allow distraction to proceed along a pre-determined vector. For example, a guiding means can include a variety of structures to engage at least one portion of at least one transmitting means, such as tongue and groove configurations. The guiding means are preferable made at least in part of a biodegradable, bioerodible or bioresorbable material. One preferred example of this aspect of the present invention is provided in **FIG. [[3]] 8**.

Amend the paragraph beginning on page 18, line 12 (paragraph [0066] of the published application), to read as follows:

In one aspect of the present invention, the activation means 22 can be engaged with the expansion means 12 at will, such as where the activation means can engage the expansion means while within the subject and then be removed at will. Preferably, the activation means is engaged with the expansion means only for activating the expansion means and then is removed. The tissues surrounding the expansion means can be structured using surgical methods known in the art so that the activating means and the expansion means can be reversibly engaged. While so engaged, the activation means can activate the expansion means. In one aspect of the present invention, the activation means can include a gear reduction structure, such as between about 1:2 and about 1:50, preferably between about 1:5 and about 1:20, so that relatively large movements in the activation means result in relatively smaller movements in the expansion means. The use of such gear reduction allows for accuracy and reproducibility in the distances chosen for distraction procedures. When the activation means is removable at will, it is preferred that the transmitting means and/or expansion means engage using structures 16, 18 that encourage unidirectional displacement, such as provided in **FIG. [[5]] 10**.

Amend the paragraph beginning on page 18, line 26 (paragraph [0067] of the published application), to read as follows:

The activation means 22 need not be permanently engaged with the expansion means. This is particularly true when the expansion means 12 is designed of biodegradable, bioerodible or bioresorbable material and intended to be left in the subject. Under those circumstances, the activation means is preferably not made of biodegradable, bioerodible or bioresorbable materials can be conveniently disengaged from the remainder of the distraction structure and removed. In this aspect, the portion of the distraction structure remaining within the subject comprises in whole or in part biodegradable, bioerodible or bioresorbable materials. In another aspect of the present invention, the activation means and expansion means are integral to each other can be disengage from one or more transmitting means and removed (see, ~~**FIG. 1**~~ **FIGS. 1-3**).

Amend the paragraph beginning on page 19, line 21 (paragraph [0070] of the published application), to read as follows:

As set forth in **FIG. [[1]] 4**, the device of the present invention is appropriately engaged in the subject. The distraction device is then modulated using the expansion means 12 and optionally the activation means 22 to cause the tissue regions to become further apart. The speed and distance by which the tissue regions are separated by the distraction device are choices to be made by the surgeon based on the particular circumstances of a particular case. A rate of distraction of about 0.5 mm to about 1.0 mm twice a day is recommended. Distraction continues until the desired distraction distance has been achieved or circumstances dictate otherwise. Then, the freshly deposited tissue, when bone, is allowed to mineralize and thus strengthen.

Amend the paragraph beginning on page 21, line 7 (paragraph [0075] of the published application), to read as follows:

In one aspect of the present invention, the stabilizer replaces at least one transmitting means and an expansion means. For example, as shown in ~~FIG. 1A and~~ **FIG. [[4]] 8** the stabilizer would be designed to replace the distal (right) transmitting means and the expansion means by having a shape and size corresponding to the combination of the distal transmitting means : expansion means combination. As such, the stabilizer would have a flange that corresponds to the metal flange that engages the notch in the proximal (left) transmitting means 10A. As shown in ~~FIG. 1E and~~ **FIG. [[4]] 8** the stabilizer 24 would correspond to the combination in the right hand of the model. In this aspect of the invention, the distal transmitting means and expansion means would be removed and replaced with the stabilizer. Optionally, the stabilizer would be designed to replace the proximal transmitting means. This is the choice of the surgeon, such as on the invasive nature of the procedure. In the procedure depicted in ~~FIG. 1~~ **FIGS. 4 and 5**, for example, the procedure is much less invasive to remove or alter the distal transmitting means and as such is preferably over removing or altering the proximal means.

Amend the paragraph beginning on page 21, line 20 (paragraph [0076] of the published application), to read as follows:

Optionally, the stabilizer can take the shape of at least a portion of the combination of the distal transmitting means : expansion means combination. In that instance, the distal transmitting means need not be removed, the expansion means is removed, and the stabilizer is engaged to the connective tissue using appropriate attaching structures 26. Optionally, the stabilizer would be designed to take the shape of at least a portion of the combination of the proximal transmitting means : expansion means combination. This is the choice of the surgeon, such as on the invasive nature of the procedure. In the procedure depicted in ~~FIG. 1~~ **FIGS. 4 and 5**, for example, the procedure is much less invasive to modulate the area of the distal transmitting means and as opposed to the area of the proximal transmitting means.

Amend the paragraph beginning on page 22, line 18 (paragraph [0078] of the published application), to read as follows:

One preferred aspect of the present invention has its basis in the procedure depicted in ~~FIG. 1~~ **FIGS. 4** and **5**. Distraction is carried out as set forth in the depicted procedure, resulting in the distraction set forth in **FIG [[1]] 5**. The expansion means 12 is removed, which results in unsupported expansion tissue that is relatively weak. A stabilizer 24 of the present invention, as discussed above, can be engaged in a variety of configurations to replace the expansion means at least in part and/or at least a portion of at least one of the transmitting means. One preferred aspect of this invention is a stabilizer made of macroporous PLA/PGA that corresponds roughly to the size and shape of the distal transmitting means, the distracted space, and the expansion means, including the flange of the expansion means that engages the slot 26 of the proximal transmitting means 10A. The distal transmitting means is optionally removed, the stabilizer engaged, and the stabilizer preferably engaged with connective tissue at the location of the distal transmitting means using appropriate attachment structures 26 or devices as described herein. As discussed above, the choice of modulating the proximal or distal transmitting means is that of the surgeon based on the particular circumstances of the case at hand, including the relative invasive nature of the locus of the transmitting means, the safety of the procedure, and the desired result.

Amend the paragraph beginning on page 23, line 11 (paragraph [0080] of the published application), to read as follows:

Furthermore, at least one stabilizer can be included in the distraction device. The stabilizer is preferably made at least in part of biodegradable, bioerodible or bioresorbable material, such as PLA/PGA, preferably macroporous strips or meshes of that material. The stabilizer can be fashioned to be attached to one side of the distraction gap and allowed to slide relatively unabated during the distraction procedure. After distraction is completed, the stabilizer can be attached to the other side of the distraction gap 30. One preferred example of this aspect of the present invention is depicted in **FIG [[4]] 7**.

Amend the paragraph beginning on page 37, line 7 (paragraph [0121] of the published application), to read as follows:

As depicted in ~~FIG. 1~~ **FIGS. 1-6**, the present invention can be used in a wide variety of distraction surgical methods and procedures. Although some of the components of the device in ~~FIG. 1~~ **FIGS. 1-6**, are represented as metal or other non-biodegradable, bioerodible or bioresorbable materials, biodegradable, bioerodible or bioresorbable materials can be used for any of these components. Preferably, the activating means 22 is not made of such biodegradable, bioerodible or bioresorbable materials, but that need not be the case. The activating device 22 is depicted without a turn-key, which when turned one rotation clockwise results in a distraction of about 0.5 mm.

C12

Amend the paragraph beginning on page 38, line 20 (paragraph [0125] of the published application), to read as follows:

FIG. [[1A]] 4 depicts as region of a skull that has undergone an osteotomy to fully free a portion of the "cheek bone." This freed region is the region to be distracted during the procedure. As shown in **FIG. 1[[B]]** depicts two portions of a transmitting means includes a macroporous sheet 32 of PLA/PGA and a flange-engaging structure 34 suitable for engaging a flange of an expansion means 12. In this aspect of the present invention the first transmitting means 10A and the second transmitting means 10B have substantially similar structures. The particular structures of the ~~transmitting means~~ flange-engaging structure 34 is provided in ~~FIG. 1L~~ **FIGS. 6A-6C**. As shown in **FIG. 1[[C]]** the flange-engaging structure 34 can be engaged to the macroporous sheet 32 using appropriate attaching devices 36, in this case bioresorbable PLA/PGA screws.

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Amend the paragraph beginning on page 39, line 3 (paragraph [0126] of the published application), to read as follows:

Two transmitting means 10 of **FIG. 1[[C]]** can be engaged with engaged with an expansion means 12 that includes flanges that engage the flange-engaging structures 34 of the transmitting means (~~**FIG. 1D**~~ **FIGS. 2-3**). In this figure, the expansion means 12 is depicted as being made of non-biodegradable, non-bioerodible or non-bioresorbable materials, but that need not be the case because the expansion means can be made of such biodegradable, bioerodible or bioresorbable materials in whole or in part. As shown in **FIG.** ~~**1E and FIG. 1F**~~ **3**, the nature of the engagement of the transmitting means and the expansion means as reversible. In the pictured aspect of the present invention, this reversible engagement is exhibited for both the first transmitting means and the second transmitting means. Thus, after distraction is accomplished, the expansion means can be disengaged from the remainder of the distraction device and removed. It is relatively simple to remove the expansion means from a subject as opposed to the transmitting means. Thus, there is a reduced amount of cumulative trauma that the subject is exposed to. ~~**FIG. 1G depicts the**~~ The proximal transmitting means : expansion means : distal transmitting means ~~that~~ has been trimmed and configured for use on the osteotomy depicted in **FIG. [[1A]] 4**. Note that the proximal transmitting means has been altered from its planar configuration.

Amend the paragraph beginning on page 39, line 18 (paragraph [0127] of the published application), to read as follows:

~~**FIG. 1H** depicts the~~ The transmitting means has a heat malleable nature, and a ~~of a transmitting means. The proximal~~ transmitting means is contacted with water hot enough to induce malleability of the material and the shape of the material ~~is~~ changed to conform to the shape of the region to which it will be attached. As shown in **FIG. [[1I]]** 4 ~~and **FIG. 1J**~~, the distraction device is depicted in place at the site of osteotomy prior to distraction. The distraction device includes heat-malleable materials that have been molded to the contours of the attachment points of the distraction device. The transmitting means 10 are secured to the skull using PLA/PGA screws in holes drilled into the bone. During a distraction procedure, the implementation of the distraction device would be complete. Distraction would be accomplished by engaging the expansion means 12 with an activation means 22 to gradually increase the distraction distance.

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Amend the paragraph beginning on page 40, line 1 (paragraph [0128] of the published application), to read as follows:

FIG. [[1K]] 5 depicts the distraction device after distraction has taken place. This figure depicts a mock-up skull, thus the distraction space has not been filled with distraction tissue. At this point in the procedure, the expansion means 12 would be removed by disengaging the expansion means 12 from the transmitting means 10, such as by engaging the activation means 22 to decrease the length of the expansion device. The expansion means can be removed using surgical procedures, preferably endoscopic procedures. If the expansion means is made in whole or in part of biodegradable, bioerodible or bioresorbable materials, then the expansion means can optionally be removed.

C16

Amend the paragraph beginning on page 40, line 9 (paragraph [0129] of the published application), to read as follows:

Optionally, at least one stabilizer 24, 28 can be inserted into, over or around the expansion space and appropriately secured such that the distracted tissue is mechanically stabilized (**FIG. [[2]] 7** or **FIG. [[3]] 9**). Such stabilizer(s) are preferably made at least in part of biodegradable, bioerodible or bioresorbable material, such as PLA/PGA, preferably macroporous PLA/PGA. In one aspect of the present invention, the stabilizing means can engage structures on the transmitting means 10A (**FIG. [[3]] 9**). In one aspect of the present invention, the stabilizing means of **FIG. [[2]] 7** and **FIG. [[3]] 9** can be combined. In addition, guiding means 20 can be used during distraction or after distraction to guide or stabilize the distraction device (**FIG. [[4]] 8**). The guiding means is preferably made in whole or in part of a biodegradable, bioerodable or bioresorbable material. As shown in **FIG. [[4]] 8**, as preferred aspect of the present invention is a guiding means that engages both the first and second transmitting means, but that is not a requirement of the present invention. For example, the guiding means can be attached to a tissue structure in proximity to the distraction site, such as bone.

Amend the paragraph beginning on page 40, line 22 (paragraph [0130] of the published application), to read as follows:

In one aspect of the present invention ~~Alternative~~ alternative structures of **FIG. [[5]] 10** depict[[s]] a[[s]] unidirectional distraction device that includes engaging structures 18 such as those in "shark's tooth" configurations and mating structures 16 to match the engaging structures such as indentations or holes (such as those in macroporous structures) to allow substantially unidirectional sliding of the transmitting means and can act to stabilize the distraction device. Preferably, the engaging structures and/or the mating structures are made in whole or in part of biodegradable, bioerodible or bioresorbable materials.